

EXHIBIT 2

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Securities and Exchange Commission
Washington, D.C. 20549

Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2004

Commission file number 001-6351

Eli Lilly and Company

An Indiana corporation

I.R.S. employer number 35-0470950

Address: Lilly Corporate Center, Indianapolis, Indiana 46285

Telephone number, including area code: (317) 276-2000

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Name of Each Exchange On Which Registered</u>
Common Stock	New York and Pacific Stock Exchanges
Preferred Stock Purchase Rights	New York and Pacific Stock Exchanges
8-3/8% Notes Due December 1, 2006	New York Stock Exchange
6.57% Notes Due January 1, 2016	New York Stock Exchange
7-1/8% Notes Due June 1, 2025	New York Stock Exchange
6.77% Notes Due January 1, 2036	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is an accelerated filer as defined in Exchange Act Rule 12b-2. Yes ☒ No ☐

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter (Common Stock): approximately \$68,515,400,000

Number of shares of common stock outstanding as of February 15, 2005: 1,132,720,819

Portions of the following documents have been incorporated by reference into this report:

<u>Registrant's Document</u>	<u>Parts Into Which Incorporated</u>
Annual Report to Shareholders for fiscal year ended December 31,	Parts I, II, and IV

2004

Proxy Statement dated March 8, 2005

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We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

Item 3. Legal Proceedings

We are a party to various currently pending legal actions, government investigations, and environmental proceedings, and we anticipate that such actions could be brought against us in the future. The most significant of these matters are described below. While it is not possible to predict or determine the outcome of the legal actions, investigations and proceedings described below, we believe that, except as otherwise specifically noted below with respect to the U.S. Zyprexa and Evista patent litigation, the Zyprexa product liability litigation, and the U.S. marketing practices investigation involving Zyprexa, Prozac, and Prozac Weekly, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to our consolidated results of operations in any one accounting period.

Zyprexa Patent Litigation

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy) and Teva Pharmaceuticals (Teva) have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa in various dosage forms and formulations (including the Zydis® formulation) several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid, not infringed, or unenforceable. In April 2001, we filed suit against Zenith in the U.S. District Court for the Southern District of Indiana seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004 and we are awaiting a ruling from the trial court. Regardless of the trial court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals.

In October 2004 we were notified that Barr Laboratories, Inc. (Barr) submitted an ANDA seeking permission to market the Zydis formulation of Zyprexa, asserting that our patents covering Zydis are invalid, not infringed, or unenforceable. In December 2004 we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's patent challenges are without merit. That suit has now been stayed pending the decision of the trial court in the Zenith/Reddy/Teva case described above.

We believe that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In May 2004, Egis-Gyogyszergyar, a generic pharmaceutical manufacturer, challenged the validity of our Zyprexa compound and method-of-use patents (expiring in 2011) in Germany. We currently anticipate a decision from the German Patent Court in 2006. In addition to our patents, we have data package exclusivity in Germany through September 2006. We are vigorously contesting the legal challenge to this patent. We cannot predict or determine the outcome of this litigation.

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Other Patent Litigation

In October 2002, we were notified that Barr had submitted an ANDA with the U.S. FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. Recently, Barr has also asserted that the method-of-use patents are unenforceable. On September 28, 2004, the U.S. Patent and Trademark Office issued to us a new patent (expiring in 2017) directed to pharmaceutical compositions containing raloxifene. Barr has challenged this patent, alleging that the patent is invalid, unenforceable, or will not be infringed. This patent has been added to the lawsuit. The suit is in discovery and the trial is now scheduled to begin in February 2006. While we believe that Barr's claims are without merit and expect to prevail, it is not possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, Pfizer Inc. filed a lawsuit in the United States District Court in Delaware against us, Lilly ICOS LLC, and ICOS Corporation alleging that the proposed marketing of Cialis for erectile dysfunction would infringe its newly issued method-of-use patent. In September 2003, the U.S. Patent and Trademark Office, on its own initiative, ordered that Pfizer's patent be reexamined. The Delaware suit has been stayed pending the outcome of the reexamination. Previously, Pfizer's corresponding European method-of-use patent was held invalid in the first stage of an opposition proceeding in the European Patent Office. Pfizer has appealed that decision, and in February 2005, the Technical Board of Appeal of the European Patent Office revoked Pfizer's method-of-use patent in its entirety. The U.K. Court of Appeal has also held the U.K. counterpart to this patent invalid. Litigation relating to the corresponding patent is also pending in Australia, Brazil, Canada, Mexico, New Zealand, and South Africa. We intend to vigorously defend this litigation and expect to prevail. However, it is not possible to predict or determine the outcome of this litigation and therefore we can provide no assurance that we will prevail.

Product Liability Litigation

We are currently a defendant in a variety of product liability lawsuits in the United States involving primarily Zyprexa, diethylstilbestrol ("DES") and thimerosal.

We have been named in approximately 140 product liability cases in the United States involving approximately 360 claimants alleging a variety of injuries from the administration of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The suits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa, and many of the suits also allege that we improperly promoted the drug. We are vigorously defending these suits. All the federal cases, involving approximately 330 claimants, have been or will be transferred to The Honorable Jack Weinstein in the U.S. District Court for the Eastern District of New York for consolidated and coordinated pretrial proceedings. Two cases requesting certification of nationwide class actions on behalf of those who allegedly suffered injuries from the administration of Zyprexa were filed in the U.S. District Court for the Eastern District of New York on April 16, 2004, and May 19, 2004, respectively. The cases seek damages for alleged personal injuries and also seek compensation for medical monitoring of individuals who have taken Zyprexa. A lawsuit was also filed that requests a class action on behalf of Iowa residents who took Zyprexa, and that case has been transferred to the federal court in New York. In addition, we have entered into agreements with various plaintiffs' counsel halting the running of the statutes of limitation (tolling agreements) with respect to more than 3,050 individuals who do not have lawsuits on file and may or may not eventually file suits. This provides counsel additional time to evaluate the potential claims. In exchange, the individuals have agreed not to file suits in state courts and the

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Plaintiffs Steering Committee agreed to dismiss the personal injury claims in the two pending nationwide class actions. The class action claims seeking medical monitoring for Zyprexa patients are not affected by this agreement.

In December 2004, we were served with two lawsuits brought in state court in Louisiana on behalf of the Louisiana Department of Health and Hospitals, alleging that Zyprexa caused or contributed to diabetes or high blood-glucose levels and that we improperly promoted the drug. In these actions, which we have removed to federal court, the Department of Health and Hospitals seeks to recover the costs it paid for Zyprexa through Medicaid and other drug benefit programs and the costs the department alleges it has incurred and will incur to treat Zyprexa-related illnesses.

In early 2005, we were served with four lawsuits seeking class action status in Canada on behalf of patients who took Zyprexa. The allegations in these suits are similar to those in the litigation pending in the United States.

The number of product liability lawsuits and tolled claims relating to Zyprexa continues to increase, and we cannot predict at this time the additional number of lawsuits and claims that may be asserted. As noted, we are vigorously defending this litigation. However, product litigation of this type is inherently unpredictable, with the risk of excessive verdicts not justified by the evidence. Accordingly, it is possible that the ultimate resolution of the Zyprexa product liability litigation could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In approximately 125 U.S. actions involving approximately 200 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed DES during pregnancy.

We have been named as a defendant in approximately 340 actions in the U.S., involving approximately 1,020 claimants, brought in various state courts and federal district courts on behalf of children with autism or other neurological disorders who received childhood vaccines (manufactured by other companies) that contained thimerosal, a generic preservative used in certain vaccines in the U.S. from the 1930s until approximately 2000. We purchased patents and conducted research pertaining to thimerosal in the 1920s. We have been named in the suits even though we discontinued manufacturing the raw material in 1974 and discontinued selling it in the United States to vaccine manufacturers in 1992. The lawsuits typically name the vaccine manufacturers as well as Lilly and other distributors of thimerosal, and allege that the children's exposure to thimerosal-containing vaccines caused their autism or other neurological disorders. We strongly deny any liability in these cases. There is no credible scientific evidence establishing a causal relationship between thimerosal-containing vaccines and autism or other neurological disorders. In addition, we believe the cases should not be prosecuted in the courts in which they have been brought because the underlying claims are subject to the National Childhood Vaccine Injury Act of 1986. Implemented in 1988, the Act established a mandatory, federally administered no-fault claims process for individuals who allege that they were harmed by the administration of childhood vaccines. Under the Act, claims must first be brought before the U.S. Court of Claims for an award determination under the compensation guidelines established pursuant to the Act. Claimants who are unsatisfied with their awards under the Act may reject the award and seek traditional judicial remedies.

We have obtained product liability insurance from commercial carriers providing coverage with respect to the claims involving the products noted above, subject to deductibles, self-insurance and coverage limits. However, there can be no assurance that the coverage amounts will be sufficient to cover all exposures or that the carriers will not assert defenses to coverage. In addition, as a result of external events, product liability insurance has become much more difficult to obtain. Consequently, product liability claims could produce exposures that we would manage largely as self-insured risks.

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Marketing Practices Investigations

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received subpoenas seeking additional documents in July 2003, July 2004, and August 2004. We have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. We continue to cooperate with the government and are currently in advanced discussions to resolve the matter. In the fourth quarter of 2004 we recorded a provision for \$36.0 million, which we believe will be sufficient to resolve the matter.

In March 2004, the office of the U.S. Attorney for the Eastern District of Pennsylvania advised us that it has commenced a civil investigation relating to our U.S. marketing and promotional practices with respect to Zyprexa, Prozac and Prozac Weekly. We are cooperating with the U.S. Attorney in this investigation and are providing a broad range of documents and information relating to the investigation, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. It is possible that other Lilly products could become subject to this investigation and that the outcome of this matter could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of this matter or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position. We have implemented and continue to review and enhance a broadly based compliance program that includes comprehensive compliance-related activities designed to ensure that our marketing and promotional practices, physician communications, and remuneration of health care professionals comply with promotional laws and regulations.

In August 2003, we received notice that the staff of the SEC is conducting an investigation into the compliance by Polish subsidiaries of certain pharmaceutical companies, including Lilly, with the U.S. Foreign Corrupt Practices Act of 1977. The staff has issued subpoenas to us requesting production of documents related to the investigation. We are cooperating with the SEC in responding to the investigation.

Other Matters

In March 2001, we received a subpoena, issued at the request of the Commonwealth's attorney for the Commonwealth of Massachusetts, for production of documents related to pricing and Medicaid reimbursement of our products in Massachusetts. We are not the only pharmaceutical company to receive such a request. We cooperated with the inquiry and have received no further requests. We believe that all of our practices have been lawful and proper.

In 2003, three counties in New York (Suffolk, Rockland, and Westchester) sued us and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the counties overpaid their portion of the cost of pharmaceuticals. In 2004, Nassau County and New York City filed similar suits. The suits seek monetary and other relief, including civil penalties and treble damages. The five New York suits have been transferred to the U.S. District Court for the District of Massachusetts for pretrial proceedings (along with several other suits to which Lilly is not a party). Litigation activity in the New York cases has been stayed pending a decision on a motion to dismiss. A motion to dismiss that was filed by all of the defendants in the Suffolk County case has been granted in part and denied in part. Our individual motion to dismiss has been granted in part, and we are awaiting a ruling on the remaining issues. Because of the similarities of the New York cases, the court's ruling in the Suffolk County case will likely set a precedent in the other cases. In July 2004, Central Alabama Comprehensive Healthcare, Inc. filed a similar suit in Alabama relating to Public Health.

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Service pricing. The suit seeks injunctive and monetary relief. The allegations in the lawsuit are based on a report issued by the Office of the Inspector General for Health and Human Services (OIG) that was subsequently withdrawn by the OIG because it was based on flawed data. We and the other defendants have filed motions to dismiss, which are pending. While we are vigorously defending all these cases, given their early procedural stage, we cannot predict or determine the outcome of this litigation.

During 2004 we, along with several other pharmaceutical companies, were named in one consolidated case in Minnesota federal court brought on behalf of consumers alleging that the conduct of pharmaceutical companies in preventing commercial importation of prescription drugs from outside the United States violated antitrust laws and one case in California state court brought by several pharmacies in which plaintiffs' claims are less specifically stated, but seem to be substantially similar to the claims asserted in Minnesota. The Minnesota case seeks a class action certification. Both cases seek restitution for alleged overpayments for pharmaceuticals and an injunction against the allegedly violative conduct. We and the other defendants have filed a motion to dismiss in the Minnesota case, which is pending. The magistrate judge has recommended that the motion to dismiss be granted as to the federal claims and denied as to the state law claims. In the California case, the court has granted a motion to dismiss by the defendants but permitted the plaintiffs to re-file their complaint, which plaintiffs have now done. While we intend to vigorously defend these suits, given their early procedural stage, we cannot predict or determine the outcome of this litigation.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, we have been designated as one of several potentially responsible parties with respect to the cleanup of fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup.

We are also a defendant in other litigation and investigations, including product liability and patent suits, of a character we regard as normal to our business.

Item 4. Submission of Matters to a Vote of Security Holders

During the fourth quarter of 2004, no matters were submitted to a vote of security holders.

Part II**Item 5. Market For the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

You can find information relating to the principal market for our common stock and related stockholder matters in our 2004 Annual Report under "Selected Quarterly Data (unaudited)," at page 28 (page 20 of Exhibit 13), and "Selected Financial Data (unaudited)," at page 29 (page 21 of Exhibit 13). That information is incorporated in this report by reference.